يهدف دبلوم اليقظة الدوائية إلى تقديم المعرفة لطلاب الدراسات العليا حول التيقظ الدوائي (PV) وفوائد المنتجات الدوائية فى سوق العمل بناءً على معرفتهم للخلفية الدوائية وسمية الأدوية. أيضا يتم تدريب الطلاب على إقتراح إستراتيجيات لأفضل النتائج العلاجية مع الحد الأدنى من المخاطر. ويجب على الطلاب معرفة التطورات المستجدة في هذا العلم الجديد لتكون لديها المهارة بما يكفي للتعامل مع العصر الجديد للسيطرة على الأدوية. والتأكد من أن الطلاب لديهم المعرفة والمهارات اللازمة التي تمكنهم من تطوير الكفاءة المهنية في التعرف على مختلف جوانب ردود الفعل السلبية للأدوية ومراقبة سلامة الأدوية وتيقظ العقاقير وتحليلها ومناقشتها. أيضا ستتم دراسة اللوائح والإرشادات الخاصة باليقظة الدوائية في الإتحاد الأوروبي والولايات المتحدة وكندا وسوف تمكن دبلومة اليقظة الدوائية المتدربين من إستخدام الطرق الإحصائية المختلفة فى مجال الإحصاء والتحليل. وتوفر الدبلوم أيضًا لطلبة الدراسات العليا معرفة أساسية عن علم الأدوية الوبائي الذي يتضمن تصميمات دراسية مختلفة ومتعددة ويجب تزويد الطلاب بجميع المعلومات والمهارات اللازمة للطب المبني على الأدلة والبراهين. ويشرف على هذا البرنامج قسم الممارسة الصيدلية والصيدلة الإكلينيكية. تبين الجداول التالية المقررات الدراسية والساعات المعتمدة وكذلك الدرجات الخاصة بكل مقرر.

الفصل الأول

Code	Course title	Credit		Course Assessment			
		Lect	Pract	Class work	Pract exam	Written exam	Total
PHP 791	Pharmacovigilance-I	3	1	20	30	150	200
PHP 792	Pharmacoepidemiology-I	2	1	20	30	100	150
PHP 793	System-based adverse drug reaction-I	2	1	20	30	100	150
PHP 794	Medical Biostatistics	2	--	20	--	80	100
PHP 795	Evidence Based Medicine	2	--	20	--	80	100
Total Credits		11	3	**Total Marks**			**700**
		14					

الفصل الثاني

Code	Course title	Credit		Course Assessment			
		Lect	pract	Class work	Practical exam	Written exam	Total
PHP 796	Pharmacovigilance-II	3	1	20	30	150	200
PHP 797	Pharmacoepidemiology-II	2	1	20	30	100	150
PHP 798	System-based adverse drug reaction-II	2	1	20	30	100	150

PHP 799	Research project	-	4	--	200	--	200
	Total Credits	7	7		**Total Marks**		**700**
		14					

Program Courses

PHP 791 : PHARMACOVIGILANCE-I (3+1)

Course Description

This course is designed to deliver knowledge to the postgraduate students on Pharmacovigilance (PV) and risk benefit balance of marketed products based on their knowledge of the pharmacological and toxicological background of the drugs. Also, students are trained to suggest strategies for the best therapeutic outcomes with minimum risks. It will cover the following topics: PV development, basics in PV science and monitoring safety in clinical trials as well as from preclinical testing data. Phases of clinical trials will be addressed with emphasis on safety monitoring. Spontaneous reporting system will be discussed including specified system from EU, USA and Canada.

PHP 792: PHARMACOEPIDEMIOLOGY-I (2+1)

Course Description

The course deals with applications and principles of pharmacoepidemiology including the international standards for the appropriate literature review, along with the advances in clinical research with the increasing use of systematic review and meta-analysis. It explores different study designs and starting from simple questionnaires and surveys up to sophisticated experimental study designs as randomized controlled clinical trials and other study designs used in the field of Pharmacoepidemiology.

PHP 793: SYSTEM-BASED ADVERSE DRUG REACTION-I (2+1)

Course Description

The course aims to help students to develop appropriate knowledge and skills in drug-induced disease in a system-based manner. The following topics will be addressed per each system: causative agents, epidemiology, mechanisms, clinical presentation, morbidity and mortality, and finally prevention and management. The following system ADRs will be covered: Cardiovascular system, endocrine system, respiratory system and bone, joint and muscle ADRs.

PHP 794: MEDICAL BIOSTATISTICS (2+0)

Course Description

Course starts with simple descriptive statistics through inferential one with the goal of understanding the use of statistics in signal detection and PV. Furthermore, studying biostatistics is crucial to understand clinical as well as experimental trials on drug safety and efficacy. Descriptive statistics would include data description (charts/ numeric), measures of location and spread, standard deviation and normal distribution. Proper data collection through confounding and matching and different study designs will be addresses. Inferential statistics will discuss concepts and calculation methods of probability, risk and odds. Concept of confidence interval will be discussed. Difference of two population means will be studied.

PHP 795: EVIDENCE BASED MEDICINE (2+0)

Course Description

This course is intended for students to acquire and develop both the knowledge and the skills for evidence-based medicine (EBM). During this course student will use concepts obtained in previous epidemiology courses as they are applied to help solving clinical problems. Health professionals make numerous decisions when they provide care to patients. These decisions should be informed by the best evidence available from sound clinical research and patients' values and preferences. Therefore, health professionals need to acquire knowledge and develop skills to determine the validity, the meaning and the applicability into practice of clinical research evidence findings.

PHP 796: PHARMACOVIGILANCE-II (3+1)

Course Description

This course will address monitoring of drug safety in clinical trials and drug development. Methods and regulations for periodic safety update reports will be discussed. Furthermore, risk/benefit assessment in PV. Regulation and guidelines for PV in EU, USA, and Canada will be studied, Harmonization procedures as per each and equivalents will be also covered.

PHP 797: PHARMACOEPIDEMIOLOGY-II (2+1)

Course Description

The course deals with applications and principles of the observational study designs including the analytical and descriptive study methods such as: case control, cohort, longitudinal observations, cross sectional, case serious & case reports and all other study designs used in this field of pharmacoepidemiology.

PHP 798: SYSTEM-BASED ADVERSE DRUG REACTION-II (2+1)

Course Description

The course aims to help students to develop appropriate knowledge and skills in drug-induced disease in a system-based manner. The following topics will be addressed per each system: causative agents, epidemiology, mechanisms, clinical presentation, morbidity and mortality, and finally prevention and management. The following system ADRs will be covered: dermatological ADRs, gastrointestinal ADRs, hematological ADRs, neurological and psychiatric ADRs.

PHP 799: RESEARCH PROJECT (0+4)

Course Description

Diploma trainees must conduct their research project in parallel to the theoretical part along the academic semester / year. Students will choose research topics after intensive open discussions during a symposium organized by the department in the presence of professors, and every student presents his/her idea in an interactive manner with the professors. Students will develop their projects throughout the semester under the supervision of a staff member which may contain data search, practical work or both. Students will give presentations at the end of the semester and submit a hard copy of the project which will be evaluated together with a presentation judged by an examination committee.